JUN 2 6 2014

510(k) SUMMARY

Submitter Name:	Precision Spine, Inc.
Submitter Address:	2050 Executive Drive Pearl, MS 39208
Submitter Contact Information:	Tel: 601-420-4244 ext. 128 Fax: 601-420-4033 Email: mike.dawson@precisionspineinc.com
Submitter Contact Person:	Michael C. Dawson, Esq.
Date Summary Prepared:	May 27, 2014
Device Trade or Proprietary Name:	Sure-Lok C Extended Tab Pedicle Screw System
Common Name:	Orthosis, Pedicle Screw Spinal System
Classification Name:	Pedicle Screw System, Class II per 21 C.F.R. § 888.3070
Product Codes	MNI MNH
Classification Panel:	Orthopedic and Rehabilitation Devices Panel
Predicated Devices:	Precision Spine/Spinal USA PSS System (K092128) Precision Spine/Spinal USA PSS System (K073240)
Type of Submission:	Special 510(k)
Basis for Submission:	Modification

Device Description:

The Sure-Lok C Extended Tab PSS System is a top-loading, multiple component, posterior spinal fixation system which consists of cannulated and non-cannulated pedicle screws, straight and pre-curved rods, and locking cap screws. All components are available in a variety of sizes to match more closely the patient's anatomy. The Sure-Lok C Extended Tab PSS System is suitable for the following procedures: open, mini-open, percutaneous MIS approach, or a combination of any during the same procedure. All components are made from medical grade stainless steel, titanium or titanium alloy which comply with such standards as ASTM F-138, ASTM F-136, ISO5832-1 or ISO5832-3. All components are supplied clean and "NON STERILE."

Indications For Use:

The Sure-Lok C Extended Tab Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The Sure-Lok C Extended Tab Pedicle Screw System is also intended for non-cervical pedicle screw fixation for the following indications: severe spondylolisthesis (grades 3 and 4 of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. It is also intended for the following indications: trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); spinal tumor; pseudarthrosis; and failed previous fusion.

Performance Data:

Consistent with FDA's guidance document entitled "Use of Standards in Substantial Equivalence Determinations" (March 12, 2000) and "Guidance for Industry and FDA Staff - Recognition and Use of Consensus Standards" (September 17, 2007), Precision Spine is including this statement that the Sure-Lok C Extended Tab Pedicle Screw System complies with the following recognized standards instead of providing the test reports demonstrating compliance with these standards: ASTM F-138, ASTM F-136, ISO5832-1, ISO5832-3, and ASTM F1717-12. These are the same standards with which the cleared Pedicle Screw System's, K092128 and K073240, complied.

A Data Standards Form (FDA Form 3654) is provided in Section 21 herein for each listed recognized consensus standard.

Change From Predicate:

The purpose of this submission is to make modifications to the components of the Pedicle Screw System cleared in K092128 and K073240. The standard construct is modified by the slightly increasing the length of the extended tab screw. In addition, the edges of the rods have been modified from being chamfered on both edges to tapered on one end and hex on the other end. The hex end provides optimal engagement in the rod inserter for insertion into the extended tab pedicle screw.

The Sure-Lok C Extended Tab Pedicle Screw System has the same intended use and fundamental scientific technology as our previously cleared Pedicle Screw System devices. The primary changes are:

1. Long-Arm Cannualeted Screw:

   The Long-Arm cannulated screw (SLCLXXXX) was cleared under K092128. The following are descriptions of key features of the proposed extended tab screw as compared to the predicate device:

   The size offerings are identical. Proposed extended tab screw is also made from Ti-6Al-4V ELI per ASTM F136 and type II color anodized. The assembly process and subcomponents are the same with the exception of the tulip design (head part on the drawing). The length of the tab has been increased. The tulips have the same outer diameter, the same tulip geometry, thread form. The height of the tulip that will remain implanted after the tabs are removed has not changed and is identical to the predicate. The proposed extended tab screw is slightly longer and the proximal geometry differs. These tabs are removed once the set screws have been tightened to their final torque. This change is made to support optional surgical approaches. This modification does not have implications on the function of the final construct.

2. The straight and lordotic rods:

   Ø5.5mm Straight and lordotic rods were originally cleared under K073240. The following are descriptions of key features of the proposed straight and lordotic rods as compared to the predicate device:

   All predicate and proposed rods are offered in Ø5.5mm diameter. The predicate straight rods (110-5XXX) are offered from 40mm-160mm in 10mm increments, as well as 180mm, 200mm, 250mm, 400mm, and 450mm. The proposed straight rods (48-ST-55XXX) are 35-80mm in 5mm increments, 90-130 in 10mm increments, as well as 200mm and 300mm lengths. The predicate lordotic rods (100-5XXX) are offered from 35-80mm in 5mm increments, 90-150mm in 10mm increments, as well as 180mm and 200mm lengths. The proposed lordotic rods (48-CU-55XXX) are offered from 35-80 in 5mm increments and 90-150mm in 10mm increments. The predicate rods have chamfered edges. The proposed rods have one tapered end and one hex end. The hex end engages the rod inserter (48-9005) for insertion into the extended tab pedicle screw. When implanted, the placement of the set screw will be medial to the hex end and tapered end, therefore the ends will not be load bearing and do not affect the strength of the construct. This chage is made to provide optimal engagement with the rod inserter and the rods. This modification does not have implications on the function of the final construct.

Substantial Equivalence:

Sure-Lok C Extended Tab Pedicle Screw System has the same intended use and similar indications, principles of operation, and technological characteristics as the Pedicle Screw Systems. The minor differences in the Sure-Lok C Extended Tab Pedicle Screw System do not raise any new questions of safety or effectiveness. Thus, the Sure-Lok C Extended Tab Pedicle Screw System is substantially equivalent to its predicate devices.

Conclusion:

The overall technology characteristics and mechanical performance data lead to the conclusion that the Sure-Lok C Extended Tab Pedicle Screw System is substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 26, 2014

Precision Spine, Incorporated
Mr. Michael Dawson
Director of Regulatory Affairs
2050 Executive Drive
Pearl, Mississippi 39208

Re: K141397
Trade/Device Name: Sure-Lok C Extended Tab Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH
Dated: May 27, 2014
Received: May 28, 2014

Dear Mr. Dawson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K141397

Device Name

Sure-Lok C Extended Tab Pedicle Screw System

Indications for Use *(Describe)*

The Sure-Lok C Extended Tab PSS System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The PSS System is also intended for non-cervical pedicle screw fixation for the following indications: severe spondylolisthesis (grades 3 and 4 of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. It is also intended for the following indications: trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); spinal tumor; pseudarthrosis; and failed previous fusion.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Zane W. Wyatt
Division of Orthopedic Devices

This section applies only to requirements of the Paperwork Reduction Act of 1995.

"DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW."

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human
Services Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA)
Staff PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

PSC Publishing Services (301) 443-6740 EF